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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/598,255	04/20/2007	Chee Keong Phuah	3869/050 US	1948

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EXAMINER	
WANG, CHANG YU	

ART UNIT	PAPER NUMBER
1649	

MAIL DATE	DELIVERY MODE
11/23/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/598,255	PHUAH ET AL.	
	Examiner	Art Unit	
	Chang-Yu Wang	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 September 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *1-48* is/are pending in the application.

5a) Of the above claim(s) *1-24* is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *25-48* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☒ The drawing(s) filed on *22 August 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/22/06,6/9/09,9/14/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application/Election/Restrictions

1. Applicant's election without traverse of Group II (claims 25-48) in the reply filed on 9/20/11 is acknowledged.

Claims 1-48 are pending. Claims 1-24 are withdrawn without traversed from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 9/20/11. Claims 25-48 are under examination in this office action.

Claim Objections

2. Claims 25, 31, 33-37, 43, 45-48 are objected to because of the following informalities: CPAP and ECG are not common abbreviations in the art. Applicants are required to spell out CPAP and ECG at the first usage. Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 25-26, 29-38, and 41-48 are rejected under 35 U.S.C. 102 (b) as being anticipated by US 6029665 (Berthon-Jones, issued on Feb 29, 2000, as in IDS).

Claims 25-26, 29-32, 34-38, 41-44 and 46-48 are drawn to a CPAP apparatus which, in addition to providing CPAP therapy, determines a patient's cardiac condition and a CPAP apparatus which, in addition to providing CPAP therapy, determines a patient's cardiac condition and provides cardiac treatment, the apparatus comprising a controller and a sensor for detecting pressure in the patient's CPAP mask, wherein the controller: senses the patient's cardiogenic pressure oscillations; and uses the sensed cardiogenic oscillations to determine the patient's cardiac condition. Dependent claims are directed to the controller identifying a central apnea event and determining the patient's cardiac condition based on the known association of central apneas and cardiac morbidity (claims 26 and 38), the controller sending a signal to the patient or physician or recording an arrhythmia (claims 29 and 41), the controller determining cardiac timing (claims 30 and 42), the controller adjusting the patient's stroke volume and the CAPA treatment pressure (claims 31 and 43), the controller analyzing determining the patient's pulse transit time (claims 32 and 44), the controller analyzing the cardiogenic oscillations against ECG waveforms to determine changes in the patient's pre-ejection period (claims 33 and 45), the controller assisting cardiac function (claims 34-35 and 46-47), and the controller using cardiogenic oscillation information for managing triggering of a bi-level CPAP apparatus (claim 48).

Berthon-Jones (US 6029665) teaches a CPAP apparatus which, in addition to providing CPAP therapy, determines a patient's cardiac condition and a CPAP

apparatus which, in addition to providing CPAP therapy, determines a patient's cardiac condition and provides cardiac treatment, the apparatus comprising a controller and a sensor for detecting pressure in the patient's CPAP mask, wherein the controller: senses the patient's cardiogenic pressure oscillations; and uses the sensed cardiogenic oscillations to determine the patient's cardiac condition as in instant claims 25-26, 29-32, 34-38, 41-44 and 46-48 (see figures 1, 2, 5, 7 and 14-16; col, 5-6; col. 13-18; col.18-20, claims 7-13, in particular). Berthon-Jones (US 6029665) also teaches an apparatus for the provision of constant level, bi-level or autosetting continuous positive airway pressure (CPAP) treatment, the apparatus comprising: a turbine controllable (i.e. controller) to provide a supply of breathable gas at desired pressures elevated above atmospheric pressure; a conduit receiving said breathable gas; a mask coupled with the conduit to provide said breathable gas to the entrance to the patient's airway; means for applying an oscillatory pressure waveform of known frequency to the patient's airway; transducer means for measuring respiratory air flow from the patient to derive an air flow signal; and processor means for determining that the airway is patent if there is a component of said air flow at said known frequency induced by said oscillatory pressure waveform, and for causing the turbine to produce a desire pressure of breathable gas in response thereto, wherein said processor high pass filters said air flow signal to reject components due to respiration, and further analyzes the filtered signal for the presence of a periodic component corresponding to the cardiogenic air flow as in claims 25-26, 29-32, 36, 37, 42-44, 46-48 (see figures 1, 2, 5, 7 and 14-16; col, 5-6; col. 13-18; col.18-20, claims 7-13, in particular in particular). Berthon-Jones

(US 6029665) teaches that the controller records an arrhythmia as in claims 29 and 41 (see col.14, in particular), Berthon-Jones (US 6029665) also teaches that the controller determines cardiac timing as in claims 30 and 42 (col. 16-17, in particular) and adjusts the patient's stroke volume and the CAPA treatment pressure as in claims 31 and 43 (see col. 13-17, in particular). Berthon-Jones (US 6029665) teaches that the CAPA apparatus also comprises means for measuring patient cardiac rate to derive a cardiac rate signal, and said processor also receives said cardiac rate signal and compares the rate with the transformed air flow signal to identify cardiogenic air flow as in claims 44-45 (see figures 1, 2, 5, 7 and 14-16; col, 5-6; col. 13-18; col.18-20, claims 7-13, in particular).

Berthon-Jones (US 6029665) also teaches an apparatus for determining patency of the airway of a patient, the apparatus comprising: means for measuring respiratory air flow from patient to derive an air flow signal; and processor means for analyzing said air flow signal to detect presence of any cardiogenic air flow, and if present, then declaring the airway patent. Berthon-Jones (US 6029665) teaches that the processor high pass filters the air flow signal to reject components due to respiration, and further analyzes the filtered signal for the presence of a periodic component corresponding to the cardiogenic air flow, and the processor performs the analysis on the basis of conducting a Fourier transformation of the filtered air flow signal as in claims 29-32, 36, 37, 42-44, 46-48 (see figures 1, 2, 5, 7 and 14-16; col, 5-6; col. 13-18; col.18-20, claims 7-13, in particular). Berthon-Jones (US 6029665) teaches that the apparatus also comprises means for measuring patient cardiac rate to derive a cardiac rate signal, and

wherein said processor also receives said cardiac rate signal and compares the rate with the transformed air flow signal to identify cardiogenic air flow as in claims 44-45 (see col. 13-18, in particular). Berthon-Jones (US6029665) also teaches Inspection of the corresponding electrocardiogram to determine and confirms the cardiogenic oscillations to determine the change in patient's pre-ejection such as phase-locked with the heartbeat, or at exactly double the cardiac rate as in claims 33 and 45 (see col.13-14, in particular). Thus, claims 25-26, 29-38, and 41-48 are anticipated by US 6029665 (Berthon-Jones).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 25, 27-28, 37 and 39-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6029665 (Berthon-Jones, issued on Feb 29, 2000, as in IDS) in view of Ayappa et al. (Chest, 1999. 116: 660-666, as in IDS).

Claims 25, 27-28, 37 and 39-40 are drawn to a CPAP apparatus which, in addition to providing CPAP therapy, determines a patient's cardiac condition and a CPAP apparatus which, in addition to providing CPAP therapy, determines a patient's cardiac condition and provides cardiac treatment, the apparatus comprising a controller and a sensor for detecting pressure in the patient's CPAP mask, wherein the controller: senses the patient's cardiogenic pressure oscillations; and uses the sensed cardiogenic oscillations to determine the patient's cardiac condition. Dependent claims are directed to the controller using cardiogenic oscillations in only the middle to later portion of exhalation to determine the patient's cardiac condition (claims 27-28 and 39-40).

US 6029665 (Berthon-Jones) is as set forth above in section under the rejection 102 but fails to teach that the controller uses cardiogenic oscillations in only the middle

to later portion of exhalation to determine the patient's cardiac condition as in claims 27-28 and 39-40.

Although US 6029665 (Berthon-Jones) does not teach the use of cardiogenic oscillations in only the middle to later portion of exhalation to determine the patient's cardiac condition, Ayappa et al. teach that cardiogenic oscillations also were seen intermittently during quiet exhalation in apnea-free periods and cardiac-induced oscillations may relate to the relaxation of thoracic muscles during central apnea and is impeded by high muscle tone during obstructive apnea (see p. 660, abstract, in particular).

It would have been obvious to one of ordinary skill in the art at the time the instant invention was made to use cardiogenic oscillations in only the middle to later portion of exhalation to determine the patient's cardiac condition in the method of US 6029665 (Berthon-Jones). The person of ordinary skill in the art would have been motivated to do so with an expectation of success because Ayappa et al. teach that cardiogenic oscillations also were seen intermittently during quiet exhalation in apnea-free periods and the presence of cardiac-induced oscillations on the CPAP airflow signal is a specific indicator of central apnea. Thus, it is obvious to incorporate the teaching of Ayappa et al. to use cardiogenic oscillations in the mid-later portion of exhalation to determine the patient's cardiac condition in the method of US 6029665 (Berthon-Jones).

Conclusion

5. NO CLAIM IS ALLOWED.

6. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Papers relating to this application may be submitted to Technology Center 1600, Group 1649 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chang-Yu Wang, Ph.D. whose telephone number is (571) 272-4521. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 6:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker, can be reached at (571) 272-0911.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chang-Yu Wang
November 9, 2011

/Chang-Yu Wang/
Primary Examiner, Art Unit 1649